UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,043	10/20/2000	Anders Bjorklund	17810-513 (SCI-13)	8502

7590 07/16/2002

Ivor R. Elrifi, Esq.
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY and POPEO, P.C.
One Financial Center
Boston, MA 02111

EXAMINER	
BAKER, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	13

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/693,043	Applicant(s) BJORKLUND, ANDERS	
	Examiner Anne Baker	Art Unit 1632	

-- Th MAILING DATE of this communication app ars on th cov r sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

File

DETAILED ACTION

The response filed April 29, 2002 (Paper No. 12) has been entered. Applicant's election, without traverse, of Group I, Claims 1-6 in Paper No. 12 is acknowledged. The elected invention is drawn to a method for inducing *in vivo* migration of progenitor cells transplanted to the brain.

Claims 1-12 are pending in the instant application.

Claims 7-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

Claims 1-6 are examined herein.

Information Disclosure Statement

The information disclosure statement filed July 24, 2001 (Paper No. 8) fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered. Several copies of references were received. However, no PTO-1449 was received.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method for inducing *in vivo* migration of progenitor cells transplanted to the brain, said method comprising the steps of: (a) transplanting said progenitor cells to a first locus of the brain of a subject; and (b) inducing *in vivo* migration of said transplanted progenitor cells by infusing a mitogenic growth factor at a second locus of the brain of said subject. In a preferred embodiment, the progenitor cells comprise mammalian embryonic progenitor cells.

The specification fails to provide an enabling disclosure for the methods of transplantation because the specification teaches that the only use for the method is to provide a therapeutic benefit to a subject and the specification does not teach how to use the claimed methods to produce a therapeutic effect. The specification does not offer any guidance as to how this method could be used therapeutically for any disorder. No working examples demonstrate a therapeutic effect in a diseased animal for the claimed methods. The specification contemplates that the claimed method of transplantation can be used to treat various neurodegenerative diseases and other pathological conditions (p. 16, line 29 to p. 17, line 30), such as epilepsy, stroke, ischemia, Huntington's disease, Parkinson's disease, and Alzheimer's disease (p. 16, line 30 to p. 17, line 1). The specification further contemplates use of the method of transplantation to treat demyelinating and dysmyelinating disorders, such as Pelizaeus-Merzbacher disease, multiple sclerosis, various leukodystrophies, post-traumatic demyelination, and cerebrovascular accidents, as well as various neuritis and neuropathies, particularly of the eye (p. 17, lines 20-23). Accordingly, the specification must teach how to use the claimed method of transplantation to produce a therapeutic effect. However, the specification does not teach how to produce a therapeutic effect in any animal. The specification fails to provide any guidance relating to the amount of cells to inject, the site of injection, and extent of cellular persistence required to provide any therapeutic benefit for any disorder.

The claims are not enabled because the transplantation of mammalian progenitor cells, particularly embryonic progenitor cells, into a host has not been demonstrated to provide any therapeutic benefit to the host. The specification clearly teaches that the use for the transplant methods is to produce a therapeutic effect in the host. Furthermore, the claims cover using any type of progenitor cell, but the teachings in the specification are limited to using neural stem cells. However, the term "progenitor cell" encompasses a wide variety of cell types, including hematopoietic stem cells, embryonic stem cells, mesenchymal stem cells, committed progenitor and precursor cells of all cell types, etc.

The specification fails to provide an enabling disclosure for the method of cell-based therapy because methods of transplantation of neural tissue are not routinely successful and the specification does not offer adequate guidance to enable one skilled in the art to practice the claimed invention to derive a therapeutic benefit in a diseased animal. The specification teaches that the only use for the claimed claimed method of transplantation is to produce a therapeutic effect, but the specification does not adequately teach how to use the claimed method to produce such an effect. Jackowski et al. (1995) details the limitations and unpredictability associated with the transplantation of neural tissue. At page 311, column 1, paragraph 2, the reference discusses barriers to successful transplantation of neural tissue, notably the presence of molecules that actively inhibit the regeneration of mammalian CNS and PNS axons. The specification does not offer adequate guidance as to how the claimed method could be used therapeutically for the treatment of the wide variety of disorders discussed in the specification. With regard to therapy, the specification provides general teachings only, but does not provide specific guidance for using the claimed method to treat pathological conditions. The specification fails to provide guidance relating to the number of cells to inject, the site of injection, and the extent of cellular persistence required and attainable in practice, to provide a therapeutic benefit for the treatment of any pathological disorder.

Given the limited working examples, the limited guidance provided in the specification directed to achieving migration of cells transplanted into the brain, the lack of specific guidance directed to the wide variety of disorders said to be amenable to treatment using the claimed method, the lack of any showing of therapeutic benefit, the broad scope of the claims, and the unpredictability for producing a therapeutic effect upon transplantation of any type of progenitor cell, undue experimentation would have been required by one skilled in the art to practice the claimed method of transplantation to produce a therapeutic effect.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker, Ph.D. whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER